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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/996,768	12/23/97	WENDEL	A P61750US0

EXAMINER

HM32/1127

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ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 11/27/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to election communication(s) filed on 9/14/98.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) 6-9 and 16-18 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-5 and 10-15 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-18 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7 (6/10/98)
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

RESTRICTION ELECTION

Applicant's election with traverse of Group I, claims 1-5 and 10-15, drawn to biological test methods for determining immune-related data, in Paper No. 6 (filed September 14, 1998) is acknowledged. The traversal is on the ground(s) that the elected claims define a method of using the product of the non-elected claims. This is not found persuasive because the product of the non-elected claims can be used in a materially different method than that of the elected claims. For example, the non-elected product can be used for blood transfusions; replacement of cellular elements; for replacement of blood clotting factors, etc.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-9 and 16-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

PRIORITY

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

DRAWINGS

The drawings are objected to for reasons set forth on the accompanying NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW (PTO-948). Correction is required.

SPECIFICATION

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Reference to a "Microfiche Appendix": See 37CFR 1.96(c) and MPEP § 608.05. The total number of microfiche and the total number frames should be specified.

(e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet. (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.

(j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.

(k) Drawings: See 37 CFR 1.81, 1.83-1.85, and MPEP § 608.02.

(l) Sequence Listing: See 37 CFR 1.821-1.825.

INFORMALITIES

The disclosure is objected to because of the following informalities: number the **Abstract** page as page number 14; and, apparently --as-- should be added after "be" on page 4, line 6.

Appropriate correction is required.

NON-ART BASED REJECTIONS

Rejections under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claims fail to set forth clear, distinct and positive method steps; and contain non-idiomatic and confusing language. Furthermore, it is unclear whether frozen or thawed cells are used in the methods or whether thawed cell viability is required.

Recitation of "deep-frozen" is both non-idiomatic and vague. It is unclear whether "deep-frozen" means frozen at a temperature of at least -20° C, or -70° C, or -196° C, etc.

Claims 1-5 and 10-15 provide for the use of deep-frozen blood or a preparation containing deep frozen blood, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The metes and bounds of "biological test procedures" and "immune-related data" are indeterminate.

It is unclear whether "containing," "involving" and grammatical derivatives thereof is open or closed claim language.

In claim 1, line 1, insert --the-- after "containing" for proper antecedent basis.

Claim 1, line 2 lacks antecedent basis for "the blood response". Additionally, it is unclear

what "response" encompasses; whether responding "the blood" is the deep-frozen blood or a preparation containing the deep-frozen blood (and whether the deep-frozen blood is still frozen during the procedures); and, what the relationship is between the deep-frozen blood/preparation, the undefined blood response and the undefined test material. It is unclear whether the test material is an analyte to be assayed and the deep-frozen blood/preparation is a reagent specifically reactive with that test material to provide a measurable response correlative of the presence or amount of the test material in some undefined test sample.

Recitation of a "preparation" containing deep-frozen blood is vague and indefinite, e.g. is the preparation also frozen, does this refer to adding diluents and/or preservatives to whole or anticoagulated blood and then freezing the blood to produce the "preparation," etc.

Recitation of "test material" in claim 1 is vague and indefinite. It is unclear whether this material is an analyte, a sample to be tested, a reagent, etc.

Claim 2 is confusing in stating "leukocytes" are used as "the blood". Leukocytes are NOT and cannot be the same as blood. Leukocytes are a subfraction of the cellular (versus plasma) fraction of blood.

Claim 2 contains several antecedent basis problems, i.e. "a deep-frozen preparation" should be --the preparation-- (claim 1, lines 1-2); antecedent basis for "blood" and "the blood" (line 2, is "blood" (first occurrence) fresh blood which is then deep-frozen to provide "the blood" (second occurrence) which the "the deep-frozen human or animal blood" of claim 1, line 1).

Recitation of "the preparation" in claims 3 and 4 is inconsistent with the language used in

claim 2, i.e. "deep-frozen preparation," and, therefore, is confusing.

It is unclear how many cryopreservative agents are required by claim 3, e.g. at least two. See also claim 4 "clotting inhibitors".

Claims 5 and 13-15 are vague and indefinite in reciting "immune-related data" because its metes and bounds are indeterminate; the "relationship" (presumably to the test material of claim 1) is undefined (is this an allergy test), etc.

Analogous comments and criticisms apply to claims 10-12 as made *supra* of claims 3 and 4.

ART BASED REJECTIONS

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 10-15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sobota et al. (*Journal of Immunological Methods*, 203(1):1-10, April 11, 1997).

See the entire article.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-5 and 10-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Busch et al. (*The New England Journal of Medicine*, 325(1):1-5, July 4, 1991).

See the entire article, especially "Methods" on pages 1-3.

Claims 1-5 and 10-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Durrant et al. (*Cancer Research*, 54(18):4837-4840, September 15, 1994).

See the entire article, especially "Clinical Protocol" on page 4837.

Claims 1-3, 5, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Martin et al. (US 5,322,787).

See the entire document, especially col. 1, lines 1-18; col. 4, lines 46-55; col. 5, lines 40-41; and, Examples 1 and 2.

Claims 1-3, 5, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Venkataraman (*Cryobiology*, 29(2):165-174, April 1992).

See the entire document, especially the abstract and page 165.

REMARKS

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Allsopp et al. (*Journal of Immunological Methods*, 214(1-2):175-186, May 1, 1998) describes a flow cytometric method to assess antigen-specific proliferation responses of different subpopulations of fresh and cryopreserved human peripheral blood mononuclear cells. Allsopp et al. also notes the literature contains conflicting reports on the effects of cryopreservation on

PBMC subpopulations and their function.

Chemical Abstract 126:2952 (Wendel et al., Pyrogen test method, EPA 741,294) discloses a method for examining substances for pyrogenic activity. Whole blood containing preparations are brought into contact with the substances to be tested, and then the preparations are examined for the formation of endogeneous pyrogens. The preparations can contain coagulation inhibitors as well as diluents such as cell culture medium or physiological saline. Tests that measure the formation of the endogenous pyrogens include measurement of interleukin-1, interleukin-6, tumor necrosis factor, or PGE_2.

Hartung et al. (*Blood*, 85(9):2482-2489, May 1, 1995) describe the effect of granulocyte colony-stimulating factor treatment on *ex vivo* blood cytokine responses of stimulated blood taken from healthy human volunteers.

As to the Information Disclosure Statement filed June 10, 1998 (paper no. 7), the first three references have been lined out because no copies were received. It is noted that the untranslated French document 2 475 737 was listed as an "A" reference or a reference of interest only to show technical background.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol A. Spiegel whose telephone number is (703) 308-3986.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Carol A. Spiegel/November 20, 1998

Carol A. Spiegel
CAROL A. SPIEGEL
PRIMARY EXAMINER
GROUP ~~1800~~ 1600